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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|---------------------------------------|----------------------|---------------------|------------------|
| 08/978,634 | 11/25/1997 | ELAZAR RABBANI | ENZ-53(DIV-2 | 4640 |
| 28171 75 ENZO BIOCHE | 590 12/20/2006 M. INC. | EXAMINER | | |
| 527 MADISON | AVENUE (9TH FLOOR) | SHIN, D | SHIN, DANA H | |
| NEW YORK, NY 10022 | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |
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| SHORTENED STATUTORY | PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 31 DAYS | | 12/20/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | Application No. | Applicant(s) | | | |
|--|--|---|---|--|--|--|
| Office Action Summary | | 08/978,634 | RABBANI ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Dana Shin | 1635 | | | |
| Dorlad fo | The MAILING DATE of this communication app | ears on the cover sheet with | the correspondence address | | | |
| Period fo | • • | VIC CET TO EVOIDE 4 MOI | NTU(S) OR THIRTY (30) DAVS | | | |
| WHIC - Exte after - If NC - Failu Any | CHEVER IS LONGER, FROM THE MAILING DATES OF THE MAI | ATE OF THIS COMMUNICA 36(a). In no event, however, may a repl vill apply and will expire SIX (6) MONTH cause the application to become ABAN | ATION. y be timely filed IS from the mailing date of this communication. NDONED (35 U.S.C. § 133). | | | |
| Status | | | | | | |
| 1)🖾 | Responsive to communication(s) filed on 11 O | ctober 2006. | | | | |
| , — | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| | closed in accordance with the practice under E | x parte Quayle, 1935 C.D. 1 | i1, 453 O.G. 213. | | | |
| Disposit | ion of Claims | | | | | |
| 4)🖂 | 4)⊠ Claim(s) <u>275 and 283-290</u> is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| • | Claim(s) is/are allowed. | | | | | |
| • | Claim(s) is/are rejected. | | · | | | |
| | Claim(s) is/are objected to. Claim(s) <u>275, 283-290</u> are subject to restriction | and/or election requiremen | nt . | | | |
| 0)[| Claim(s) <u>273, 263-290</u> are subject to restriction | rand/or election requiremen | н. | | | |
| Applicat | ion Papers | | | | | |
| | The specification is objected to by the Examine | | | | | |
| 10) | The drawing(s) filed on is/are: a) acc | | | | | |
| | Applicant may not request that any objection to the | | | | | |
| 11) | Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex | | | | | |
| • | | diffiler. Note the attached t | ymos your en le mar le lez. | | | |
| | under 35 U.S.C. § 119 | | | | | |
| | Acknowledgment is made of a claim for foreign | priority under 35 U.S.C. § 1 | 19(a)-(d) or (f). | | | |
| a) | All b) Some * c) None of: | - h h | | | | |
| | 1. Certified copies of the priority document | | dication No | | | |
| | 2. Certified copies of the priority document3. Copies of the certified copies of the priority | | | | | |
| | application from the International Bureau | | , colved in this Hational Stage | | | |
| * (| See the attached detailed Office action for a list | | eceived. | | | |
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| Attachmer | nt(e) | , | | | | |
| _ | ce of References Cited (PTO-892) | 4) Interview Sur | mmary (PTO-413) | | | |
| 2) Noti | ce of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/ | Mail Date ormal Patent Application | | | |
| | rmation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date | 6) Other: | | | | |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 275 and 283-288, drawn to a multimeric composition comprising two elements comprising a protein and a polymer, classified in class 536, subclass 23.1, for instance.
 - If this group is elected, applicants are further required to elect a single protein from an antibody, a lymphokine, a cytokine, a hormone, a cellular matrix protein, a receptor binding protein, and a growth factor. Applicants are also required to elect a single binding matrix from polypeptide, polynucleotide, and polysaccharide. Note these not species election requirements. An election of a single protein and an election of a single binding matrix will trigger an election of readable claims among claims 284-288.
- II. Claims 289-290, drawn to a process for delivering a multimeric complex to a subject, classified in class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

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§ 806.05(h). In the instant case, the multimeric composition of group I can be used in a method of inhibiting a protein production/expression in a subject. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

The claimed proteins are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

See MPEP § 806.05(j). In the instant case, the proteins as claimed are structurally and functionally divergent. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The claimed binding matrixes are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not

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overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the binding matrixes as claimed are materially and functionally different. For instance, a polypeptide comprises amino acids while a polynucleotide comprise nucleic acids, thus, the polypeptide binds proteins while the polynucleotide binds DNAs. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species: protamine, polyglutamic acid, and polylysine in claim 287, and soluble DEAE, dextran sulfate, carboxymethyl cellulose and DEAE dextran in claim 288. The species are independent or distinct because the physical and chemical properties are different for each species. Further, it would impose a serious search burden on the examiner to search all the claimed species because the search key words are not co-extensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 275 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Potential Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

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Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin Examiner Art Unit 1635 JANE ZARA, PH.D. DRIMARY EXAMINER